In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-801V

ANA GUARDIOLA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 30, 2024

Sean Franks Greenwood, The Greenwood Law Firm, Houston, TX, for Petitioner.

Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING ON SITUS AND DISMISSING TABLE SIRVA CLAIM[1]

On July 1, 2020, Ana Guardiola filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result tetanus-diphtheria-acellular pertussis ("Tdap"), influenza ("flu"), and pneumococcal conjugate ("PCV13") vaccines administered to her on July 2, 2018. Pet. at 1, ECF No. 1. The Petition does not identify the site of administration of any of the subject vaccines, and instead alleges pain in both arms following their

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

receipt.[3] *Id.* at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

For the reasons discussed below, I find it more likely than not that Petitioner received all three vaccines in her left shoulder. However, her claim cannot meet other Table elements, as her pain and reduced range of motion ("ROM") were not limited to the shoulder in which the subject vaccines were administered. Therefore, her Table SIRVA claim is not tenable and must be dismissed (although the claim *might* be tenable under an off-Table analysis).[4]

I. Relevant Procedural History

Along with her Petition, Petitioner submitted an affidavit. ECF No. 1. Shortly after initiating her claim, Petitioner filed her medical and immunization records, followed by a statement of completion. ECF Nos. 6-7. A question was then raised regarding the validity of the entries on Petitioner's vaccination record from Walgreens and whether she, in fact, received the subject flu vaccine as alleged. *See* ECF No. 14.

In pursuit of that issue, in March 2022, Respondent filed a status report requesting additional outstanding records. ECF No. 27. This request for records included complete records from Walgreens pharmacy (noting the source of the handwritten information on the document is "unknown"), and complete records from Petitioner's primary care physician ("PCP"), including treatment notes from Petitioner's July 2, 2018 visit during which the subject PCV13 vaccination was allegedly administered. *See id.* Petitioner was subsequently ordered to produce such records. ECF No. 29. In response, Petitioner filed a status report stating that no additional records from Walgreens or her PCP exist, and the record was therefore complete. ECF No. 30.

On July 19, 2022, Respondent filed a status report requesting to file a Rule 4(c) Report, arguing that this case was not appropriate for compensation. ECF No. 31. That report was filed on October 19, 2022, and in it Respondent argued that Petitioner had failed to establish the administration site of the covered vaccinations she received on July 2, 2018. ECF No. 33. Specifically, Respondent highlighted that the Walgreens record reflects a handwritten notation that the flu and Tdap vaccines were administered in

[3] Petitioner also received a non-covered shingles (Shingrix) vaccination on July 2, 2018. Ex. 7 at 2. Petitioner is not alleging an injury associated with that vaccination, specifically.

[4] Although the parties submitted briefings on the issue of whether there was another condition or abnormality that explains Petitioner's post-vaccination symptoms, at this time, this Ruling is limited to a finding of fact regarding situs and whether her pain and reduced range of motion were limited to the shoulder in which the subject vaccinations were administered.

Petitioner's left arm, and a shingles vaccine[5] in her right. *Id.* at 5 (citing Ex. 7 at 3). Respondent asserted Petitioner's vaccination records are not certified, there is no explanation for why half of the records are handwritten when the other half is not, and there is no corresponding treatment record to establish the site of administration of Petitioner's PCV13 vaccination. *Id.* at 6.

Respondent also argued that Petitioner's medical records show her pain and reduced ROM were not limited to the shoulder in which the subject vaccines were administered. ECF No. 33 at 6-7 (citing Ex. 2 at 114-17; Ex. 3 at 55; Ex. 4 at 7-12, 18). Finally, Respondent asserted that Petitioner's records revealed other conditions or abnormalities (cervical disc disease and severe osteoarthritis ("OA") in the right acromioclavicular ("AC") joint) that may explain her post-vaccination shoulder symptoms. *Id.* at 7 (citing Ex. 4 at 11-12, 20).

Petitioner subsequently filed a status report confirming she did not have any additional evidence to submit in response to the arguments raised in Respondent's Rule 4(c) Report and she filed a motion for a ruling on the record on May 25, 2023. ECF Nos. 36-37. On July 10, 2023, Respondent filed a response to Petitioner's motion. ECF No. 38. Later that month, Petitioner filed her insurance profile from Walgreens pharmacy – which includes documentation of Petitioner's July 2, 2018 Tdap and Shingrix vaccinations, without also noting proof of her receipt of a flu vaccine that day. Ex. 15 at 88. ECF No. 40. This matter is now ripe for consideration.

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the Petition by Vaccine Act Section 11(c)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule

[5] Respondent correctly states that the shingles (Shingrix) vaccination is not covered under the Vaccine Act and Petitioner is not alleging an injury caused by her receipt of the shingles vaccination. Respondent's Report at 5, n.5.

does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014). The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Relevant Factual Evidence[6]

On July 2, 2018, Petitioner (then 72 years old) received the subject flu,[7] Tdap, and PCV13 vaccines (plus a non-covered shingles vaccine). Ex. 7 at 2; Ex. 2 at 125. Petitioner attests that she received the Tdap and flu vaccines in her left arm at Walgreens pharmacy. Ex. 1 ¶ 2; Ex. 7 at 2. Petitioner also alleges that she received the PCV13 vaccine on the same day at the Memorial Hermann Health System ("Memorial Hermann"). Ex. 1 ¶ 2; Ex. 2 at 125. Petitioner admits in her affidavit that she "cannot specifically recall into which arms [she] received the shots." Ex. 1 ¶ 2, n.1. But she began experiencing pain "in both of [her] arms at the injection sites" immediately upon their receipt. *Id.* ¶ 3.

As noted above (and reproduced below), the vaccination record from Walgreens pharmacy contains both typed and handwritten entries. The typed entries reflect Petitioner's immunization history and show she received Tdap and shingles vaccines on July 2, 2018 – but without documenting a site of administration. Ex. 7 at 2. The record also contains, however, handwritten entries noting that the subject flu and Tdap vaccines were administered in Petitioner's left arm, while the non-covered shingles vaccine was administered in her right arm. *Id.* The Walgreens pharmacy record is reproduced below:

Immunization Details

Rx Number	Store Number	Date Sold	Product
1918339	3198	11/21/2011	FLUZONE HIGH-DOSE 2011-120.5ML SYR
1988394	3198	08/22/2012	PNEUMOVAX 23 INJ 25MCG/0.5ML
2097785	3198	09/20/2013	FLUVIRIN MULTIDOSE VIAL 2013-14 5ML
2566544	3198	11/15/2017	FLUZONE HIGH-DOSE 2017-180.5ML SYR
2651568	3198	07/02/2018	BOOSTRIX INJ, 0.5ML
2651567	3198	07/02/2018	SHINGRIX 50MCG INJ(IM)SNGDSE VL10PK

Shingrix Lot 5737X exp. 1/23/21 right arm

Walgreens #03198
7634 Bellaire Blvd
Houston, TX 77036
(713) 774-2180

Fluzone Lot UI-892AB exp. 6/06/18 left arm

Boostrix Lot 7735E exp. 03/09/21 left arm

See id.

[6] I have reviewed all of the filings submitted by both parties to date. Only those facts relevant to situs and localization of symptoms will be discussed herein, although other facts may be included as necessary.

[7] Although not explicitly contested by Respondent in his Rule 4(c) Report or response to Petitioner's motion for ruling on the record, there was a question early on in the pendency of this case as to whether Petitioner received the flu vaccine at all. *See,* e.g., ECF No. 14. In light of Respondent's position, this Ruling will not otherwise determine whether Petitioner, in fact, received the vaccine (although preponderant evidence supports the determination). *See,* e.g., Ex. 7 at 2.

Also on July 2, 2018, Petitioner presented to her PCP at Memorial Hermann for an annual wellness visit. Ex. 10 at 91. Although treatment notes for this visit with her PCP do not appear in the medical records, other records nevertheless show that Petitioner received a PCV13 vaccine in her left deltoid during this visit. Ex. 2 at 125. The Memorial Hermann vaccination record is reproduced below:

> ***pneumococcal 13−valent vaccine** − 0.50 mL − IM (Left Deltoid)
> **Admin Dt/Tm:** 07/02/2018 11:45 **Ordered by:** Herrera, Carmen Marbella MD **Charted by:** Ruiz, Crissia MA **Manufacturer:** Wyeth Pharmaceutical Vaccines **Lot Number:** T85621 **Exp Dt/Tm:** 03/30/2020 00:00

See id.

The next day (July 3, 2018), Petitioner went to the emergency room ("ER") complaining of arm and neck pain, as well as "generalized body aches." Ex. 2 at 114-16. Petitioner noted she received a tetanus and shingles vaccine the day before this visit. *Id.* at 116. A physical examination showed "[r]ight shoulder tenderness" and normal ROM. *Id.* The "final diagnostic impression" was listed as myalgias and right shoulder strain. *Id.* The physician noted that her pain was "likely muscular skeletal [sic] in origin secondary to her recent vaccine[.]" *Id.* Petitioner was sent home and told to use warm compresses and over-the-counter medications to relieve her pain. *Id.*

On July 18, 2018, Petitioner's PCP called her to discuss results of unrelated laboratory work. Ex. 3 at 21. During this call, Petitioner "stated she is having pain on her arm from vaccines she had at pharmacy." *Id.* The note does not contain a description of which arm was affected or to which vaccination or vaccinations Petitioner's pain was attributed. *See id.*

Petitioner returned to her PCP on July 26, 2018, complaining of "right shoulder pain[,]" specifically, "neck pain that radiates down the right shoulder." Ex. 3 at 54-55. Petitioner reported the duration of her pain was "4 weeks." *Id.* at 55. She did not provide a description of the accident/injury that brought about such pain. *See id.* Petitioner underwent an x-ray of the right shoulder, which was consistent with severe AC joint OA; the x-ray of her cervical spine showed "mild to moderate multilevel degenerative changes of the cervical spine." *Id.* at 61-62. Petitioner was diagnosed with right shoulder pain and cervicalgia. *Id.* at 56.

On August 2, 2018, Petitioner returned to the ER "[complaining of] chest pain radiating to the bilateral arms which began earlier th[at] evening." Ex. 4 at 6. Petitioner

(through her family)[8] also reported shortness of breath and that she had "recently received injections[9] for pain[.]" *Id.* Petitioner was admitted.

During Petitioner's August 3, 2018 examination, Petitioner (through her niece) denied "any chest pain" but stated she

> has had this pain in her bilateral upper extremity associated with neck pain since she got vaccinations about 3 weeks ago at her [PCP's] office[,] this has been treated a few times with pain medications and injections however no improvement[. S]he is unable to lift both of her arms at this time has some mild numbness and tingling in bilateral upper extremity. [Petitioner] is not sure which vaccines but tetanus was one of whom [sic] it may be Pneumovax.

Ex. 4 at 17.

Petitioner underwent a neurology consultation on August 5, 2018, for "bilateral arm pain and numbness." Ex. 4 at 24. Petitioner reported she "received vaccinations for tetanus, shingles, and one other unknown vaccination" and experienced "bony pain and tenderness immediately upon vaccine administration in her [right] upper shoulder." *Id.* at 25. She was currently experiencing "painful [right] shoulder movement." *Id.* The neurologist noted that Petitioner had "severe [OA] and probable coracoacromial joint pathology producing some of her pain[;]" and Petitioner's "clinical suggestion [was] of right greater than left rotator cuff damage." *Id.* at 24.

Petitioner was discharged the same day with diagnoses of atypical chest pain (non-cardiac), right shoulder pain secondary to severe OA of the right AC joint with supraspinatus tendinopathy, and C3-C4 cervical canal stenosis with bulging cervical disc without myelopathy. Ex. 4 at 28-29. Petitioner was prescribed naproxen and gabapentin, and she received a referral to orthopedics and physical therapy ("PT"). *Id.* at 29.

On August 16, 2018, Petitioner had her initial orthopedic evaluation. Ex. 5 at 18. She reported a history of "bil[ateral] shoulder pain[,] 3 injections (2R, 1L) 7/2/18." *Id.* She stated that "the vaccines were given by on [sic] the arm" and she developed pain thereafter. *Id.* at 19. She noted her pain is constant and burning, primarily in the lateral

[8] Petitioner's medical records contain notations that she received the services of a Spanish interpreter during several of her medical visits. *See,* e.g., Ex. 3 at 23, 55.

[9] Although billing records show Petitioner received a Ketorolac injection on July 30, 2018, corresponding encounter or treatment notes for this visit cannot be located in the filed medical record. *See* Ex. 10 at 96. Such treatment thus cannot be considered in determining situs or the other contested issues in this case.

shoulder, and worse with "attempting to lift the arm." *Id.* An examination showed bilateral tenderness to palpation, severe pain with active and passive ROM, and positive impingement signs. *Id.* at 20. Petitioner was diagnosed with bilateral subacromial bursitis. *Id.* She received a Kenalog injection in each shoulder. *Id.*

Petitioner followed up with her orthopedist two weeks later, on August 30, 2018. Ex. 5 at 12. She reported improvement for the first three days following her steroid injections, but her pain "returned and is now worse than before." *Id.* Petitioner was prescribed oral steroids and subsequently underwent an MRI on September 12, 2018. *Id.* at 12, 24. The MRI of the left shoulder showed 1) a near-full thickness tear of the supraspinatus tendon, 2) biceps tendinosis, 3) a tear of the posterosuperior glenoid labrum, 4) a small glenohumeral joint effusion with synovitis, 5) moderate to severe AC degenerative arthritis, and 6) mild subacromial subdeltoid bursitis. *Id.* at 24-26. The MRI of Petitioner's right shoulder showed 1) a tear in the supraspinatus tendon, 2) a tear in the subscapularis tendon, 3) biceps tendinosis, 4) degenerative tearing of the labrum, 5) mild bursitis, 6) moderate glenohumeral effusion with synovitis, 7) moderate to severe AC degenerative arthritis, and 8) mild subacromial subdeltoid bursitis. *Id.* at 22-23.

On November 12, 2018, Petitioner followed up with her orthopedist to discuss her MRI results. Ex. 5 at 9. She reported having severe pain in the bilateral shoulders. *Id.* Petitioner's physical examination was unchanged, and she was assessed with bilateral subacromial bursitis, partial thickness rotator cuff tears, and biceps tendinosis. *Id.* at 10-11. Petitioner received repeat steroid injections in each shoulder. *Id.*

Roughly six months later, on May 2, 2019, Petitioner returned to her orthopedist reporting that her previous steroid injection "helped for about 2 weeks." Ex. 5 at 5. She stated that she "continue[d] to have a lot of pain in both shoulders, difficulty putting on her clothes. The entire shoulder hurts." *Id.* She received repeat injections in her bilateral shoulders. *Id.* at 7. No additional medical record or affidavit evidence has been submitted.

IV. Findings of Fact

A. Situs

While Respondent contends that the uncertified vaccination records in this case are insufficient to establish "which particular vaccines [Petitioner] received on July 2, 2018, or the site of those particular vaccines[,]"such arguments are unpersuasive. *See* Respondent's Report at 6; Respondent's Response at 6.

Rather, the complete vaccine administration form from Walgreens pharmacy depicts a typed entry showing Petitioner received one of the covered subject vaccines (Tdap) on July 2, 2018. Ex. 7 at 2. Although this entry does not have a corresponding typed *situs* of vaccination, it is accompanied by a handwritten entry showing that the Tdap vaccine was administered in Petitioner's left arm. *Id.* The form also shows (in a handwritten entry) that a covered flu vaccine was likewise administered in Petitioner's left arm. *Id.* A separate record depicts a typed, computerized entry supporting receipt of Petitioner's PCV13 vaccine in her left arm, also. Ex. 2 at 125.

In my experience with SIRVA cases (over 2,000 within SPU since my appointment as Chief Special Master, additional cases handled within chambers, and review of opinions issued by other special masters), I have found it often to be the case that information regarding the vaccine administration site is incorrect – especially information contained in *computerized* records, which may feature a 'dropdown' menu which may not be updated each time a separate vaccine is administered.[10] Although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply *because* they come first – and in fact the nature of their creation provides some basis for not accepting them at face value. But information contained on these kinds of records reflecting *specific action* on the part of the vaccine administrator (often at the very time of administration), such as a handwritten notation on a printed form, generally warrants more significant weight.[11]

Such handwritten notations can be rebutted of course, by additional, case-specific evidence and circumstances. For instance, in one case a petitioner's history of vaccination and subsequent injury in the same shoulder was medically documented just 13 days post-vaccination, and consistently thereafter. That petitioner also explained that she requested vaccination in her non-dominant arm. *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-0881V, 2022 WL 2284311, at *3 (Fed. Cl. Spec. Mstr. May 13, 2022). In another more recent matter, the petitioner's history was medically documented 23 days post-vaccination, and in numerous later records. And the site notation was found on "an otherwise haphazardly-completed form (containing entries listed diagonally and not in the allotted space)" – constituting a specific reason to doubt the record's reliability. *Toothman*

[10] *See,* e.g., *Mezzacapo v. Sec'y of Health & Hum. Servs.*, No. 18-1977, 2021 WL 1940435, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 2021); *Desai v. Sec'y of Health & Hum. Servs.*, No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Hum. Servs.*, No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

[11] *See,* e.g., *Schmidt v. Sec'y of Health & Hum. Servs.*, No. 17-1530V, 2021 WL 5226494, at *8 (Fed. Cl. Spec. Mstr. Oct. 7, 2021); *Marion v. Sec'y of Health & Hum. Servs.*, No. 19-0495V, 2020 WL 7054414 at *8 (Fed. Cl. Spec. Mstr. Oct. 27, 2020).

v. Sec'y of Health & Hum. Servs., No. 22-0207V, 2024 WL 2698520, at *4 (Fed. Cl. Spec. Mstr. Apr. 19, 2024).

Here, I do not find sufficient reason to doubt the entries on the relevant vaccine administration records. Indeed, the handwritten Walgreens entries here are deserving of appropriate weight – they clearly depict notations requiring specific action on the part of the vaccine administrator, and the entries are not so haphazardly executed as to cast doubt on the clarity of the record or its reliability. *See Toothman,* 2024 WL 2698520, at *4. Rather, it is credible that the vaccine administrator took the time to document by-hand each of Petitioner's administered vaccines, along with vaccine lot numbers, expiration dates, and site of administration. Ex. 7 at 2. In addition, the record reveals variation in the site of administration, adding to the overall credibility of the relevant proof. For instance, the relevant record shows that two of the three vaccinations were administered in one arm (the left arm), while the third vaccination was administered in the other. *See id.* Thus, the handwritten Walgreens vaccine administration record in this case has *some* facial reliability that Respondent has not persuasively undermined.

Additionally, Respondent appears to have misidentified proof of administration of Petitioner's PCV13 vaccine. *See* Respondent's Response at 6 (stating that the vaccine may have been administered "based on the Medicare reimbursement records," but the record does not identify the site of administration or correspond to any treatment notes). In fact, Petitioner's medical records contain a computerized entry documenting her receipt of this particular vaccine, and it shows said vaccination was administered in the left deltoid. Ex. 2 at 125. I do not have any reason to doubt the accuracy of this record.

The vaccination record evidence is thus sufficient to establish situs in this case, without looking to the contemporaneous medical records of Petitioner's post-vaccination treatment. (This is just as well, as Petitioner's medical records do not contain descriptions of which arm each subject vaccination was administered). *See,* e.g., Ex. 3 at 21; Ex. 4 at 17; Ex. 5 at 18. More so, her affidavit provides context for her lack of descriptions of situs in the contemporaneous medical records – as she admittedly could not remember in which arm or arms, she received her July 2018 vaccinations. Ex. 1 ¶ 2, n.1. I therefore find that the subject Tdap, flu, and PCV13 vaccines were more likely than not administered in Petitioner's left arm. In order for Petitioner's Table claim to succeed, she thus needed to demonstrate that her SIRVA-consistent shoulder symptoms were located in the left shoulder as a result of a covered vaccination.

B. Scope of Pain and Limited Range of Motion

The third QAI requirement for a Table SIRVA requires a petitioner's pain and reduced range of motion to be "limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii).

Respondent contests that Petitioner's pain was limited to her shoulders, generally. Respondent's Response at 6. Rather, Petitioner complained of pain all over her body, neck pain radiating to her right shoulder, and chest pain that radiated to both arms. *Id.* at 6-7 (citing Ex. 2 at 114-17; Ex. 3 at 55; Ex. 4 at 7-12, 18).

The record is largely consistent with Respondent's contention. Indeed, the day after the vaccinations, Petitioner was complaining of arm and neck pain plus *"generalized body aches"* and myalgias. Ex. 2 at 114-16 (emphasis added). She did not describe left shoulder symptoms, specifically; she instead demonstrated right shoulder findings upon examination. *See id.* Later that month (July 26, 2018), Petitioner was experiencing "neck pain that radiates down the right shoulder." Ex. 3 at 54-55. Throughout August 2018, Petitioner consistently reported *bilateral* arm pain, but often with an emphasis on the right shoulder. *See,* e.g., Ex. 4 at 6, 17 (an August 2, 2018 ER note showing chest pain radiating to the bilateral arms with neck pain); Ex. 4 at 24-25 (an August 5, 2018 neurology note of bilateral arm pain/numbness and reporting that she experienced immediate *right* shoulder pain upon vaccination and at the current time; found to have a greater pathology in the *right* than left shoulders); Ex. 5 at 18 (an August 16, 2018 diagnosis of bilateral subacromial bursitis). In addition, Petitioner's post-vaccination diagnostic procedures and treatment originally pertained to the *opposite* arm and shoulder – and presented the same way in both arms. *See,* e.g., Ex. 2 at 114-16; Ex. 3 at 54-55; Ex. 4 at 24-25, 28-29.

In the Program, special masters have found that claims involving musculoskeletal pain *primarily* occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body. *K.P. v. Sec'y of Health & Hum. Servs*., No. 19-65V, 2022 WL 3226776, at *8 (Fed. Cl. Spec. Mstr. May 25, 2022) (holding that "claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body"). But the third QAI criterion is intended to "guard against compensating claims involving patterns of pain or reduced [ROM] indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." *Grossmann v. Sec'y of Health & Hum. Servs.,* No. 18-0013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022).

Thus, special masters balance complaints about shoulder pain, and associated treatment, against evidence that the overall presentation is more systemic. *See,* e.g., *Cross v. Sec'y of Health & Hum. Servs*., No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023) (finding that "despite the notations of pain extending beyond the shoulder, Petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology"); *Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QAI criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder").

Here, Petitioner did not simply experience "stray notations" of pain extending beyond the shoulder, but whose injury was still consistent with SIRVA. *See K.P.,* 2022 WL 3226776, at *8. Rather, there is evidence that Petitioner initially complained of generalized body aches and myalgia. Ex. 2 at 114-16. And once Petitioner complained of shoulder-related complaints, such complaints or manifestations were instead originally focused on the opposite shoulder. *See,* e.g., Ex. 3 at 54-55, 61-62.

Additionally, Petitioner's pain was not found to be radiating *from* the vaccinated left shoulder – but rather was noted to originate in the neck and radiate *to* the right shoulder or begin in the chest and radiate *to* the bilateral upper extremities. *See* Ex. 3 at 54-55; Ex. 4 at 6, 17. Overall, the medical records do not consistently reflect a new injury localized to the left shoulder as the *primary* complaint, that can be isolated from other incidental complaints of pain elsewhere. Petitioner has therefore failed to establish this QAI criterion and her Table claim must be dismissed.

Conclusion and Order to Show Cause

The factual finding of a left-sided vaccine administration of covered vaccinations required Petitioner to establish that her pain was limited to that shoulder. *See* 42 C.F.R. § 100.3(c)(10)(iii) (providing that a SIRVA is limited to "the shoulder in which the intramuscular vaccine was administered"). As she has been unable to do so, Petitioner's Table SIRVA claim is therefore **DISMISSED.**

It is therefore unnecessary to resolve whether Petitioner's condition could be explained by another condition or abnormality. 42 C.F.R. §§ 100.3(a), (c)(10)(iv); Respondent's Response at 7 (challenging this criteria).

Instead at this stage, the remaining question is whether any off-Table, causation-in-fact claim might be feasible for a left-sided injury. But Respondent's briefing and my

preliminary review of the evidence has identified a potential alternative cause for the injury discussed herein (moderate-to-severe OA of the AC joint in the bilateral shoulders). And the overall nature of the complained-of symptoms is not in many ways consistent with an injury that is more shoulder-oriented.

Petitioner will be afforded one brief and final opportunity to determine whether she would like to pursue any remaining causation-in-fact claim centering on an injury in the vaccinated shoulder/arm. However, Petitioner may not formally retain an expert, or order any expert's written report, without prior consultation with Respondent and the Court. Any request for experts, when combined with this case's age, would likely support the case's transfer out of SPU for further proceedings.

Petitioner's failure to respond to this or other orders issued in this action, as well as failure to file evidence required to support his claim, will be interpreted as a failure to prosecute resulting in dismissal of Petitioner's claim. *Tsekouras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 439 (1992), *aff'd*, 991 F.2d 810 (Fed. Cir. 1993) (per curiam); *Sapharas v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b).

Accordingly, within 30 days, by no later than Wednesday, October 30, 2024, Petitioner shall show cause why her claim should not be dismissed for insufficient proof of causation-in-fact and otherwise stating how she wishes to proceed.

In the alternative, if Petitioner wishes to exit the Vaccine Program, counsel shall file the appropriate motion, Stipulation, or Notice. *See* http://www.uscfc.uscourts.gov/sites/default/files/autism/EXITING_GUIDANCE_TO_PRO_SES.pdf.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master